MINUTES OF THE 32nd MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 22nd & 23rd SEPTEMBER, 1998

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The agenda items were thereafter taken for discussion.

i. **Confirmation of the minutes of the 31st DCC meeting held on 21st & 22nd November, 1997.**

The Minutes were confirmed.

ii. **Consideration of the action taken report based on Agenda related to the 30th DCC Meeting.**

Item No. 3 : Consideration of the proposal for curtailing the number of licences required for stocking, distribution or sale of drugs.

The Agenda started from 28th DCC meeting held on 16th and 17th July, 1992. The then DCC decided that the experts standing committee consisting of the Commissioner, FDA, Maharashtra; Drugs Controller, West Bengal; Drugs Controller, Delhi; and Drugs Controller, Karnataka would give a report on the matter.

The major features of the report are to do away with separate licences for drugs specified in Schedule "C and C-I" and other than those specified in Schedule "C and C-I". It is felt that the Form 19, 19-A, 20, 20-A, 20-B and 20-BB will require minor amendments with corresponding changes in the Rules and simultaneously Form 21, 21-A, 21-B and 21-BB could be deleted.

The members recommended that the matter should be placed before DTAB for inclusion in the Drugs and Cosmetics Rules.

Item No. 11 : Consideration of inclusion of Buprenorphine in Schedule X in the Drugs and Cosmetics Rules.

The members of the 30th DCC proposed that the extent of abuse should be studied extensively in the de-addiction centres in various State Govt. hospitals. Accordingly, all the State Drug Controllers had been requested to forward a comprehensive study report on the abuse aspect of Buprenorphine product.

The secretariat did not receive any such comprehensive study report on Buprenorphine abuse except only a few comments referring that the drug Buprenorphine should be placed under Schedule "X".

The members of 32nd DCC expressed their views that no immediate action is required to be taken in the matter. Any future action in the matter will be considered only on the basis of data furnished by the State Drugs Controllers and other expert agencies.

Item No. 13 : Consideration of stocking of drugs labeled as physician's samples in residential premises and unlicensed premises.

The Agenda came in the 30th DCC meeting held on 6th and 7th September, 1995.

Consequent to the decision taken during the 30th DCC meeting, the sub-committee under the Chairmanship of the Commissioner, FDA, Maharashtra was constituted to suggest guidelines on stocking of drugs labeled as physician's samples in the residential and unlicensed premises. The relevant provisions relating to the above matter are rule 65(18) and Section 18(c) of the Drugs and Cosmetics Act and Rules thereunder.

The sub-committee proposed for certain changes in Section 18(c), rule 65(18) and certain other portions of the Drugs and Cosmetics Rules.

The report of the sub-committee was placed as Annexure II to 31st DCC meeting Agenda for circulation.

The members of 32nd DCC recommended that the sub-committee report should be placed before the DTAB for taking necessary action.

Item No. 14 : Consideration for publication of the names of the manufacturers of the not of standard quality drugs in the press and other actions to be taken.

The write-up forwarded by the DDC(I), West Zone, has been enclosed as Annexure I in 32nd DCC meeting Agenda.

The members are requested to forward their views within 3 months time, so that the same can be communicated to the experts standing committee to prescribe a rational guideline in the matter.

Item No. 17 : Consideration of powers to prosecute under DMR Act, 1954.

The Chairman of 30th DCC decided that a sub-committee to be constituted to examine the matter. However, later on this sub-committee is merged

with a high power committee to develop the ideas, policies and guidelines under DMR Act. The draft report of the high power committee was elaborated by the Joint Drugs Controller to the DCC members.

The members requested that the final report of the sub-committee may be made available to them at the earliest possible time so that a definite line of action may be decided in taking action on all matters relating to the DMR Act and Rules thereunder.

Item No. 32 : Consideration of the question whether animal food preparations which are fortified with vitamins are to be considered as 'drugs'.

The Chairman of the sub-committee Dr. K.R.Viswanathan, vide his letter No. PA/DC(LH)/98 dated the 8th September, 1998 intimated that the committee requires some more time to submit the report. The members agreed for the same.

Item No. 38 : Consideration of imported raw materials of B.P. and USP standards in respect of Calcium Pantothenate.

The main issue in the matter is to ascertain the potency of the Calcium Pantothenate. The matter has been discussed also in the meeting of the I.P. Committee.

The I.P. Committee had already suggested the microbiological assay to test the biological activity of the drug. The decision has been accepted by the members.

Item No. 47 : Consideration of the examination of the extent and conditions of exemption provided under entry No.10 of Schedule 'K' for milk preparations and cereal preparations fortified with vitamins and minerals to be used for (drugs-classification) products containing Protein hydrolysates, Vitamins and Minerals, etc.

The Agenda came for discussion in the 30th DCC meeting to classify the protein tonic preparations as 'food or drugs'. The members pointed out that a large number of such products are available in the market which have therapeutic claim but classified as 'food' since such products have exemption benefits under Schedule 'K'. On application of the provisions of the Drugs and Cosmetics Rules, the products are not under the regulatory control by the drug authorities. As the products have the therapeutic claim, the PFA authorities are also not serious to regulate such products. Thus the products are neither controlled by the drug authorities nor by the food authorities.

To examine such products from the drug as well as food angle, the 30th DCC had entrusted the Drugs Controller, Uttar Pradesh, to consult experts and give recommendation in the matter.

Since DC, U.P., could not produce any rational idea in the matter, the 31st DCC constituted a sub-committee under the Chairmanship of ADG(PFA). The members agreed to provide time till March, 1999 as desired by ADG(PFA).

Item No. 62 : Consideration of maintaining control reference samples by the cosmetics manufacturers.

The 8th Government Analyst Conference recommended that the reference samples in respect of cosmetic products should be kept by the cosmetics manufacturers. The members agreed that such a provision for maintaining control samples should be made.

However, as the standards for cosmetics were prepared by the Bureau of Indian Standards, the recommendations of the Government Analyst Conference in this regard should be referred to BIS for their perusal and opinion. Further, BIS may also deliberate about the time period for which the control samples should be retained by the cosmetic manufacturers.

Item No. 65 : Consideration of the issuance of conclusive test reports by PLIM Laboratory, Ghaziabad.

The matter could not be sorted out because of the absence of any representative from the ISM Division.

The members decided that the matter, along with the items of Agenda pertaining to ISM, is to be referred to the Joint Secretary (ISM) for necessary comments.

C. Consideration of the action taken report based on the Agenda related to 31st DCC Meeting.

Item No. 1 : Consideration of the proposal to amend Rule 64 so as to prohibit or restrict excessive concentration of Chemists Shops at a particular location.

The sub-committee report was taken for discussion. A large number of the members, specially the Commissioner, FDA, Maharashtra, felt that many of the recommendations of the sub-committee are very rigid. He specifically desired that so far as ownership is concerned, it should be open to all concerned to start and run any retail or wholesale premises.

Considering the total aspect of the sub-committee report, the Chairman requested that the Agenda should be re-examined by the sub-committee and recommendations should be forwarded along with the comments from the Chemists and Druggists Association.

Item No. 4 : Proposal regarding monitoring on quality / efficacy of the Biological products (Human / Veterinary) including veterinary drugs.

The members discussed the matter with the Head of the Standardisation Division of IVRI. DDC(I), West Zone, was requested to provide a list of vaccines which may be required to be tested at IVRI. ADC(I), IGIA, Delhi desired to know the mode and approach to be followed to send the vaccine samples to IVRI.

The IVRI representative said that testing can only be possible if the testing fees are re-imbursed by the agencies desirous for such testing.

The Chairman requested the IVRI to examine the fees structure to be levied by them in the light of the provisions given under Schedule 'B' of Drugs and Cosmetics Rules.

Finally, the members recommended that a complete write-up from IVRI on the subject may be obtained on the points discussed above.

Item No. 10 : Consideration of the proposal to amend Rules 74(j), 78(I) and 65(17)(b) of the Drugs and Cosmetics Rules 1945 for expeditious recall of impunged samples of drugs by the manufacturer and sales outlets.

The members discussed the matter in the light of the recommendations made by the 45th DTAB.

The matter was discussed from various angles like shortest possible time for effective recall, fool-proof mechanism to freeze the sale and manufacture of the impunged drugs, etc.

However, the members felt that it is very difficult to incorporate any statutory provisions in the Drugs and Cosmetics Rules relating to the time-bound recall of the drugs at the present moment.

Alternatively, the members felt that there should be uniform guidelines from the DCG(I) for the effective recall of the sub-standard drugs. The format used for recall of the sub-standard drugs by the Joint Commissioner, FDA, Maharashtra, was circulated.

The Chairman requested Commissioner, FDCA, Gujarat to look into the matter and examine the recall system followed by the FDA, Maharashtra and suggest DCG(I) in framing guidelines in the matter.

Item No. 12 : Consideration of the proposal to amend Drugs and Cosmetics Rules, 1945 to grant exemption under certain specified conditions to peripheral institutions run by the Government which are collecting whole human blood under emergency situations.

The members agreed with the proposal made by the sub-committee to include suitable clause in Schedule 'K' in Drugs and Cosmetics Rules, 1945.

Item No. 13 : Consideration of the proposal to insert Rule 148 provisions relating to safety testing of Cosmetics with minimal use of animals.

The Agenda was included in the 31st DCC meeting in relation to the decision made in the 7th Meeting of Section Committee of the BIS.

In the meeting, it was proposed that the mandatory testing on animals in respect of Cosmetics should be re-scheduled and the choice to test or not to test the products on animals may be left to the manufacturers. However, the products not tested on animals may display the statement "Not tested on animals".

The matter was referred to BIS to minimize the testing of Cosmetics on live animals for assessing harmful effects on the human body. BIS have formed the guidelines incorporating certain changes in the specifications relating to the minimal use of animals for evaluating safety of Cosmetic products which was brought to the notice of the members of the 32nd DCC.

Item No. 14 : Matters concerning grant or renewal of loan licences to manufacture Large Volume Parenterals (LVPs).

In the 31st DCC meeting, the members decided that FDCA, Gujarat and FDA, Maharashtra would forward information regarding loan licences on LVPs to enable the committee to examine the matter from the legal angle. Since the complete information could not be furnished in time, the 32nd DCC decided to reconsider the matter.

After listening to various comments, the Chairman decided that the issue will be reviewed by the Commissioner, FDCA, Gujarat and he should be assisted by the Joint Commissioner, FDA, Maharashtra. The Chairman requested Commissioner, FDA, Gujarat to furnish his report within a period of 3 months time.

Item No. 19 : Consideration of the proposal to amend relevant rule of the Drugs & Cosmetics Rules, 1945 with regard to upward revision of fee structure prescribed for grant / renewal of sales and manufacturing licences including Homoeopathic, Ayurvedic, Cosmetics and testing of drugs and enhancement of the period of sale licence.

The 31st DCC decided that the matter should be examined by a sub-committee. The sub-committee forwarded the final notification made by the Government of Maharashtra to increase the fees structure. The notification has been circulated to all the members and the members have taken a decision that similar notification may be considered for the approval of DTAB.

Item No. 23 : Consideration of the proposal to amend Schedule F-II in respect of standards for surgical dressings, viz. Gauge and bandages.

The Agenda came up in the 31st DCC meeting. As per Schedule F-II for the manufacture of gauge and bandages, cotton yarns count between 20 tex and 25 tex for wrap and count between 25 tex to 30 tex for weft has to be used to maintain the higher weight of 30.5 gms. per sq.m. and 57.5 gms. per sq. m. respectively. The other Pharmacopoeia viz. BP, USP and EP prescribe cotton yarn 40s count for weaving the gauge and bandage cloth and the required weight is only to maintain a minimum weight of 14 gms. per sq. m. for gauge and minimum 28 gms. per sq. m. for bandage. Cost-wise the gauge and bandage manufactured with cotton yarn count of 40s is cheaper by 50%. It has been suggested that the standard of bandage cloth and the gauge should be made at par with the standard of other pharmacopoeia such as BSP, USP and EP.

The 31st DCC members desired to generate comments on this issue from BIS.

Since there is no reply received from BIS, the members of the 32nd DCC desired to pursue the matter with the BIS to have a complete report in the matter.

Item No. 24 : Proposal regarding inclusion of "Good Clinical Trial Regulations in India" under Schedule "Y" of the Drugs & Cosmetics Rules.

The members recommended that the proposal should be placed before DTAB for necessary approval.

Item No. 25 : A proposal regarding rationalization of Fixed Dose Combinations moving in the market with various proportion in respect of (a) Dextropropoxyphene with Paracetamol, (b) Ibuprofen with Paracetamol and (c) Diclofenac Sodium with Paracetamol.

The action taken in the matter has been circulated to all the members. The members expressed their desire to know the report of the core group and any further action taken to rationalize the Fixed Dose Combinations mentioned in the Agenda.

The Chairman requested the Joint Drugs Controller (India) to intimate the members regarding the decision taken, if any, by the core group committee and other authorities in respect of such Fixed Dose Combinations.

Item No. 31 : Consideration of inclusion of all Schedule "G" drugs in Schedule "H" and the resultant omission of Schedule "G" from the Rules.

The sub-committee constituted by the 31st DCC requested for some more time to complete the report.

The members agreed to provide time till 31st December, 1998 as desired by the sub-committee.

Item No. 36 : Proposal to amend Item No. 56 of Banned Drugs Notification vide GSR 633(E) dated the 13th Septemeber, 1995.

The proposal was related to the Banned Drugs Notification No. GSR 633(E) dated 30th September, 1995 in relation to the banning of Fixed Dose Combination of drug standards which are prescribed in the First Schedule of Drugs and Cosmetics Act related to Ayurveda, Siddha and Unani drugs. The Commissioner, FDCA, Gujarat has made a proposal that the hard gelatin capsules are covered under the definition of drugs as per section 3 (b) of the Drugs and Cosmetics Act, 1940 and some of the Ayurvedic drugs are filled in such capsules and marketed. The proposal of the Commissioner, FDCA, Gujarat was that such permission cannot be granted unless suitable amendment is made in Item No.56 of the banned drug list.

The members of 31st DCC decided that Adviser (ISM) should be asked to include hard gelatin capsule in their Schedule as many Ayurvedic medicines are now sold in capsule form.

Joint Secretary (ISM) intimated that hard gelatin capsule is not an ASU drug and has requested that the Ministry of Health & Family Welfare should take immediate action to rescind entry No.56.

The Committee was of the view that if 'Hard Gelatin Capsules' are used by Ayurvedic manufacturers, then its standards need also be incorporated

under the Ayurvedic Pharmacopoeia also. This is because 'Hard Gelatin Capsules' are used only as a component to contain the active materials.

Item No. 41 : **Proposal for modification of the content of the prescription under Rule 65(10).**

The proposal came in view of the Hon'ble Supreme Court of India's judgement in the case of Poonam Verma Vs. Aswin Patel relating to Rule 65(10) of the Drugs and Cosmetics Rules. It was proposed to have some modifications in the prescriptions made by the Registered Medical Practitioners and the members of 31st DCC desired that some comments should be received from the Medical Council of India. However, no such comments have been received from the Medical Council of India till date.

During discussion, members desired that no further action in the matter is immediately needed as the matter is still subjudice.

31st DCC SUPPLEMENTARY AGENDA :

Item No. 2 : **Reconsideration of the constitution of expert standing committee for indepth examination for amending provisions of Drugs and Cosmetics Act, 1940.**

The Commissioner, FDCA, Gujarat has proposed the constitution of the Experts Standing Committee as follows :

1. Shri S. P. Adeshara, Commissioner, FDCA, Gujarat - Chairman
2. Shri B. R. Wadhawan, ADC(I) - Member Secretary
3. Shri S. S. Venkata Krishnan, DC, Kerala - Member
4. Shri K. B. Rup, DC, Orissa - Member
5. Shri S. N. Tripathi, DC, Goa - Member
6. Shri V. M. Bobade, Jt. Commr., FDA, Maharashtra - Member
7. Shri P. N. Saraswat, DC, Rajasthan - Member
8. Shri M. Munivelu, DDC(I), Tamilnadu - Member

32nd DRUGS CONSULTATIVE COMMITTEE CENTRAL AGENDA ITEMS :

Item No. 1 : Gradation of the penalties for offences under the Drugs and Cosmetics Act and Rules thereunder and setting up special court for cases where CrPC is not required to be followed.

The members discussed the matter in detail. The Section 27 of the Drugs and Cosmetics Act related to the penalties of offences for manufacture, sale, etc. in contravention of Chapter IV is to be examined well before making any recommendation on the penal offences. In some of the States, as in West Bengal and Uttar Pradesh, the penalties have been made much stringent by providing "Life imprisonment" in clause 'a' of Section 27. Thus, provisions for compounding of offences should be recommended only after the careful study of the particular section of the Act.

The members from Karnataka, Kerala, Gujarat were in favour of the proposal for the compounding of offences under the provisions of the Drugs and Cosmetics Act and Rules whereas, the Drugs Controller, Tamilnadu expressed his views that the compounding of offences is not possible under the provisions of the Drugs and Cosmetics Act.

The Chairman finally decided that the matter may be examined and recommended by a sub-committee consisting of the following members :-

1.	The Drugs Controller, Karnataka	-	Chairman
2.	The Drugs Controller, Goa	-	Member Secretary
3.	The Drugs Controller, Tamilnadu	-	Member
4.	The Drugs Controller, Rajasthan	-	Member
5.	The Drugs Controller, Punjab	-	Member
6.	The Drugs Controller, Haryana	-	Member
7.	The Commissioner, FDA, Gujarat	-	Member

Item No. 2 : Deletion of clause (a) from the provisions of Chapter IV under "Extent and conditions of exemption" – entry 13 of Schedule K of Drugs and Cosmetics Rules (House Hold Remedies).

The matter regarding the introduction of OTC drugs in the Drugs and Cosmetics Rules has been discussed at length. On the basis of the recommendations made by the members, the Chairman desired that the

following sub-committee will examine the matter and give their recommendations for taking necessary action in the matter :-

1. The Jt. Drugs Controller (India), CDSCO (Hqrs) - Chairman

2. The Drugs Controller, Karnataka - Member Secretary

3. The Commissioner, FDA, Maharashtra - Member

4. The Commissioner, FDCA Gujarat - Member

5. The Drugs Controller, Goa - Member

6. The Drugs Controller, Orissa - Member

7. The Drugs Controller, Delhi - Member

8. The Drugs Controller, Kerala - Member

The sub-committee will have power to co-opt the other members from various expert groups.

The sub-committee will examine the views on the house-hold remedies or OTC drugs, and recommend to adopt the policies to make a list of house-hold remedies or OTC drugs to be included in the Drugs and Cosmetics Rules. Also, the sub-committee will examine the Schedule 'H' drugs from the angle of taking out the drugs from the said schedule which are reported to be sold as OTC drugs in the developed countries. In the course of discussion the sub-committee may also examine the possibility of introducing the definition of OTC drugs in the appropriate place of the Drugs and Cosmetics Rules.

Further, the sub-committee will give their comments on the advertisement policy of OTC drugs through television, radio and newspapers.

Item No. 3 : **Consideration of proposal to implement uniform price control on the Drugs and Drug Formulations.**

The **Joint Secretary, NPPA** explained the norms followed by them to fix up the prices for the bulk drugs and drug formulations under the provisions of DPCO,1995. He also requested the members to monitor the prices of the drugs moving in the market. Many of the members intimated that they do not receive the Notifications on the price approval issued by NPPA. The Joint Secretary assured the members that he will look into the matter and see that all the Notifications are issued and received directly by the State Licensing Authorities. The members from Tamil Nadu, Kerala

and Karnataka desired for changes in certain paras in DPCO, 1995 to enable them to prosecute the offenders. The Joint Secretary requested them to send their proposals directly to him to consider the matter.

The Chairman suggested that if they desire, the NPPA may circulate their Notifications, minutes, etc. to all the State Drugs Controllers through the Zonal Officers of CDSCO.

Item No. 4 : To change the designation from Inspectors to a suitable designation befitting importance of their role to perform the work under the Drugs and Cosmetics Act and Rules thereunder.

The members desired that the proposal to change the designation of the Inspectors may be examined by the Expert Standing Committee to assess the feasibility of the proposal in relation to the performance of the duties of the Inspectors under the provisions of the Drugs and Cosmetics Act and Rules thereunder.

Item No. 5 : Inspection of the retail premises by the authorized citizen groups and the resultant inspection reports to be acted upon by the Drugs Controllers.

The members desired that before taking any further action to empower the authorized citizen groups for the inspection of the retail premises, the matter is to be discussed in their respective State Advisory Committee. The Chairman also agreed with the proposal made by the members and he requested the members to forward their comments in the matter within three month's time.

Item No. 6 : Proposal for making standards for diagnostic kits and reagents.

The issue for laying down the guidelines for the manufacture, quality control parameters and identification of nodal testing laboratories, etc. has already been discussed in the Expert Committee meeting held on 10th July, 1998 at Nirman Bhawan, New Delhi.

In the meeting, the committee proposed for three sub-committees to examine the quality control parameters of the diagnostic kits and reagents which are presently manufactured and imported in the country. Once the reports of the sub-committees are received by the Drugs Controller General (India), a decision will be taken on the basic issues related to the quality parameters to be followed for the imported and indigenously manufactured diagnostics.

The members have also been requested to give their views for laying down the guidelines for the manufacture and quality control of the imported and indigenously manufactured diagnostics.

The attending member, Dr. (Mrs.) Sokhey of National Institute of Biologicals, New Delhi recommended that each lot of the imported critical kits should be tested before being released in the market. At present, NIB, New Delhi is testing the critical kits.

For necessary evaluation of the kits, Dr Sokhey stated that the laboratory requires 500 test kits for HIV and HBsAg alongwith the following documents :-

(a) WHO, FDA Certificates in respect of the specification details and GMP aspects of the kits and reagents.

(b) Product Inserts.

(c) Results of evaluation or clinical study done in the country of origin.

(d) Quality assurance report on the batch and batch release certificate.

Shri Eswaran, the invited expert form M/s. Boehringher Mannheim Diagnostics – (Nicholas – Piramal group) deliberated on the Biochemistry and Clinical Chemistry reagents. He emphasized that all the biochemistry kits should be tested in an accredited laboratory like National Institute of Biologicals or National Institute of Communicable Diseases or All India Institute of Medical Sciences or National Institute of Immunology, etc. He also proposed, if allowed, they would like to install the Chemilumenescent System and other testing equipments to National Institute of Biologicals against free of cost. This will help in the standardization and quality control of the kits marketed in India.

Shri Satyaki Ray, the expert consultant in the field of Diagnostics stated that all the importer of the critical kits should have internal quality control laboratory, a qualified person to train and serve the prospective clients sufficient storage space and cold chain facility right from the importation to the customer's point should be provided. He also listed out the requirements for imports –

(a) Purpose and principle of test.

(b) Physical description of the kits.

(c) Pack size.

(d) Expiry date and date of manufacture.

(e) Storage conditions.

(f) Names of countries where the kits are currently marketed and registered.

(g) GMP / ISO Certification.

(h) Details of internal quality control laboratory at the importer's place for HIV and Hepatitis markers.

The Chairman finally decided that all the recommendations and comments will be considered in the next follow-up meeting of the Diagnostic Expert Committee and guidelines wil be framed for future action in the matter.

Item No. 7 : Proposal for prohibiting the use of Propylene Glycol in pharmaceutical formulations.

The control of the quality of the propylene glycol containing formulations has been discussed in the meeting. Most of the attending members suggested that it would be better if suitable method could be identified for the detection of Diethylene Glycol in propylene glycol containing formulations.

Accordingly, the Chairman requested Dr. P. D. Sethi, expert Consultant Analyst to suggest his views in the matter. Dr. Sethi illustrated a method which is reproduced below for the attention of the members :

DETECTION OF DIETHYLENE GLYCOL / ETHYLENE GLYCOL CONTAMINATION IN GLYCERIN, PROPYLENE GLYCOL OR FORMULATIONS CONTAINING EITHER GLYCERIN OR PROPYLENE GLYCOL :

Abbreviations used:- Glycerine – Gly; Propylene Glycol – **PG**; Diethylene Glycol – **DEG**; Etheylene Glycol – **EG**.

Salient Features:- The test uses non-halogenated mobile phase (WHO has banned the use of chloroform).

2. The detection reagent is simple to prepare and absolutely non-toxic.
3. The detection procedure is one-step and easy to follow.

Procedure:

Layer:- Pre-coated TLC plates, silicagel 60 F_{254} (plastic or aluminium back) preferably of Merck because of its easy availability.

Size of the Plate:- 20 x 20 cm or 10 x 10 cm depending on the numbers of samples under analysis.

Mobile Phase:- Toluene-acetone-5 M ammonia (05 : 85 : 10 v/v).

Size of the chamber for development:- Rectangular glass chamber with lid and absolutely flat bottom. 20x20 or 10x10 cm. (if the glass chambers are not available, ordinary glass bottle (round) of 500 ml capacity with screen cap or clip-in cap is recommended).

Preparations of Solutions:-

(1) 2.0% solution of glycerine or PG under analysis in methanol.

(2) 0.2% solution of DEG or EG in methanol.

Spotting of solutions:- Use 5 ul graduated (5x1 ul) glass capillary (available with M/s. Top Syringe India Ltd.). The capillary may be tapped from non-graduated end for keeping the size of spot to minimum while spotting the solutions.

Detection Reagent:- 0.5% solution of potassium permanganate in either used or freshly prepared mobile phase.

Note :- Use of mobile phase (used or fresh) for preparing solution of potassium permanganate prevents spots of the substances from dissolving or being distorted. **DO NOT USE WATER TO MAKE SOLUTION OF POTASSIUM PERMANGANATE.**

After development, remove the plate and allow it to dry in air for about 10 minutes. The presence of small amount of ammonia remaining in the sheet after air drying is recommended as it speeds up oxidation of glycols. Pour potassium permanganate solution in a Petri-dish and immerse the developed and air dried plate into the detection reagent for enough to cover the surface of the sheet. All the sheet to remain in the reagent solution for 2-3 minutes. (The detection reagent is stable and can be used to stain number of developed sheets). Remove the stained sheet and allow it to dry in the air. Oxidised spots of different glycols shall appear as yellow against light purple back-ground.

Note:- The spots starts appearing after some time, the first one to appear is of Gly in 5 minutes the formation is complete in 30 minutes, the last one to appear is that of DEG. It is therefore, recommended that the plate should be examined after 30 minutes.

Observation:- Any secondary spot other than the principal spot obtained with solution (1) is not more intense than the spot obtained with solution (2) i.e. of DEG or EG.

Limit of detection:- 0.5% of DEG or EG present either in Gly or PG or formulations containing Gly or PG as vehicles.

Order of movement of spots in the chromatogram with their HRF(Rfx100)

Glycerine	25
Diethylene glycol	33
Ethylene glycol	33
Propylene glycol	55
Sucrose	00
Sorbitol	00

HRF values shall vary depending on the temperature, humidity or saturation of the chamber.

General Precautions:- Sample and standards must be run on the same plate as intensities from different sheet cannot be compared because of difference in staining and fading.

(2) Detection limits can further be lowered by increasing the volume of the sample to be spotted.

(3) This method clearly separates DEG or EG from other glycols (Gly or PG), through separation of DEG from EG is not good. It is not of significant as both DEG and EG are equally toxic and are well separated from non-toxic glycols (Gly and EG).

Reference :- This method is based on the collaborative studies by Six WHO Collaborating Laboratories : Allen S. Kenyon el al J.AOAC International, 81(1), 44-50, 1998. Address of the Laboratory : US, FDA, Division of Testing and Applied Analytical Development, St. Louis, MO63101, USA.

The Chairman suggested that the members should examine the method of analysis proposed by Dr. Sethi in relation to have a suitable solution in the matter and forward their comments within three month's time.

Item No. 8 : Proposal to adopt 'IS 4707 (Part II) 1993' List of raw materials generally not recognized as safe for use in cosmetics under the Drugs and Cosmetics Rules, 1945.

The members discussed on the list of raw materials generally not recognized as safe for use in cosmetics. On the basis of the recommendations made by the members, the Chairman concluded that the negative list of raw materials IS 4707 (Part 2) may be incorporated in the Drugs and Cosmetics Rules, 1945 so as to ensure that no harmful chemicals are used in the manufacture of cosmetics. The members further deliberated that the said specifications could be adopted by amending the Rule 145 D which relates to 'Prohibition of manufacture of cosmetics containing mercury compounds'.

Item No. 9 : Inclusion of standards for liquid foundation make-up (IS:14318 1996) in Schedule 'S' of the Drugs and Cosmetics Rules, 1945.

The BIS has finalized the specifications for 'Liquid Foundation Make-up' vide IS:14318:1996. The specifications include general requirements (description, ingredients, color pigments), mode of packing and marking, sampling, test methods (determination of pH, stability, suspended solids, microbiological tests, etc.) for the said preparation.

The members recommended the inclusion of the above specifications for liquid foundation make-up in Schedule 'S' of the Drugs and Cosmetics Rules.

Item No. 10 : Consideration of the proposal to constitute State Advisory Committee / Board under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder.

The Hon'ble Prime Minister set up a Commission to review the administrative laws under the Chairmanship of Shri P.C.Jain to enquire into various problems faced by the trade and industry and grievances of the consumers. The Commission was concerned about the problems faced by the consumers in respect of the quality of drugs and also on account of unwarranted prices charged by retail and wholesale dealers. The Commission recommended that the State Advisory Committees / Boards in all the States / Union Territories should be properly represented by the Consumer Organisations.

The members discussed the matter and decided that all the States and Union Territories shall constitute such State Advisory Committees / Boards through their own legislations.

Item No. 11 : Consideration of the proposal to amend Rule 96 to indicate special warnings about the usage of the drug and contra-indications on the label of the drug.

The members discussed on the matter that the consumers should be made aware about the usage of the drug. The label of the drug should indicate specials warnings in a legible manner. The members suggested and recommended that all possible information and warnings should be supplied alongwith the inner most packing of drugs for the consumer guidance.

Item No. 12 : Monitoring on the movements of banned drugs.

The members agreed to forward a quarterly report on the monitoring of the drugs and formulations banned under Section 26A of the Drugs and Cosmetics Act.

Item No. 13 : To follow quality control parameters and specifications mentioned in Indian Pharmacopoeia.

The members agreed to look into the matter and to ensure that Indian Pharmacopoeia 1996 would be procured by the manufacturers and testing laboratories.

Item No. 14 : Availability of Morphine tablets to the cancer patients.

The item relating to the availability of morphine tablets to the cancer patients has been introduced by the Chairman. Smt. Reva Nayyar, Joint Secretary (Admn. and N.C.), Department of Revenue, Ministry of Finance, illustrated the matter that in response to a Public Interest Litigation matter, the Narcotic Control Board has been asked to find out a suitable simplified procedure, so that morphine tablets are easily available to the out door cancer patients, but the procedure should not dilute the concern of the possibility of the abuse of the drug.

In this connection, she requested the members to examine the possible amendments of the relevant rules and schedules of the Drugs and Cosmetics Act and Rules thereunder to facilitate the sale of morphine tablets by the recognized institutions to the out door cancer patients.

A draft guideline has been circulated to all the members on the special provision relating to the availability of morphine tablets by recognized medical institutions.

The Chairman decided that a sub-committee with the following members may examine the issue and forward their recommendations :-

1. Smt. Reva Nayyar, Jt. Secretary (Admn. & N.C.) - Chairman

2. Shri Ashwini Kumar, Jt. Drugs Controller(I) – Member Secretary

3. The Commissioner, FDA, Maharashtra - Member

4. The Commissioner, FDCA, Gujarat - Member

5. The Drugs Controller, Delhi - Member

Item No. 15 : Policy regarding licensing of Blood Banks.

The Ministry of Health and Family Welfare drafted a National Blood Policy in order to have an uniform policy of Blood Banks throughout the country. A copy of the draft National Blood Policy has already been forwarded to all the State Licensing Authorities for their comments.

Dr. V.N.Sardana, Joint Director (Blood Safety), NACO, explained the draft national policy on the Blood Banking System and requested the members to forward their comments. Since the time limit for the discussions was very short, the Chairman requested all the members to forward their comments directly to NACO after consulting their State authorities, specifically State Blood Councils.

Item No. 16 : Submission of reports on narcotic drugs.

The members agreed to submit the necessary information within the stipulated time period.

Item No. 17 : Proposal for consideration of amendment of Scheduel 'M' on Good Manufacturing Practices (GMPs) and requirements of premises, plants and equipments.

The Agenda relating to the Good Manufacturing Practices on production and quality assurance has been introduced by the Chairman. Schedule 'M' pertaining to the GMP and requirements of premises, plants and equipments was incorporated under the Drugs and Cosmetics Rules in the year 1988. WHO with a view to control the quality of drugs moving in the inter-country markets devised a 'Certification Scheme' on the quality of the pharmaceutical products available in the international commerce. Most of the countries are participating in the 'WHO Certification Scheme' through their respective National Health Authorities. WHO in its 28th meeting, adopted the revised text of the 'Good Practices' in the manufacture and quality control of drugs and published revised guidelines from time to time. It has, now become necessary to review the existing

Schedule 'M' under the Drugs and Cosmetics Rules and to modify it at par with the WHO requirements as India is also one of the participating country to WHO Scheme.

To sensitize the members, the Chairman requested Dr. Vinay Nayak, the invited member to deliberate on the modern aspects of GMP.

Dr. Nayak illustrated the GMP principles of TGA-Australia; MCC-South Africa; and European guidelines. Finally, the Chairman concluded that to review the present Schedule and to ensure the requirements of WHO standards, the DCC may constitute two separate sub-committees.

The GMP sub-committee will include the following members for giving their recommendations on necessary guidelines on premises, plants, machineries, equipments, validation process, record keeping, etc. :-

1. The Commissioner, FDA, Maharashtra	-	Chairman
2. The DDC(I), West Zone	-	Member Secretary
3. The Commissioner, FDCA, Gujarat	-	Member
4. The Drugs Controller, Delhi	-	Member
5. The Drugs Controller, Goa	-	Member
6. The Drugs Controller, Karnataka	-	Member
7. The Drugs Controller, Kerala	-	Member
8. Dr. Vinay Nayak, Expert Consultant	-	Member

The GLP sub-committee will include the following members for giving their recommendations on necessary guidelines on testing, premises, equipments, quality assurance methods, record keeping, etc. :-

1. The Jt. Drugs Controller (India) (Hqrs)	-	Chairman
2. The Director, CIPL	-	Member Secretary
3. The Director, CDL	-	Member
4. The Drugs Controller, Andhra Pradesh	-	Member
5. The Drugs Controller, Rajasthan	-	Member

6. The Drugs Controller, Orissa - Member

7. Dr. P. D. Sethi, Expert Consultant - Member

The GLP sub-committee will also recommend the guidelines to be followed by the approved laboratories.

STATE AGENDA ITEMS

GUJARAT

Item No. 18 : Consideration for the amendment of Rule 85(2) so that powers to the licensing authority cannot be challenged by the appellate authority or the Court.

The members discussed the matter and decided that the issue relating to the amendment of Rule 85(2) may be initially examined by the Expert Standing Committee. Accordingly, the Chairman decided that the Expert Standing Committee may examine the matter and forward their recommendations.

KERALA

Item No. 19 : Consideration to provide a separate system of licensing for the blood transfusion units requiring exemptions of the regular system.

The proposal relating to the Separate Licensing System for the blood transfusion units requiring exemptions has been introduced by the Drugs Controller, Kerala. The members deliberated on the issue and decided that National Blood Council should be involved to take the decision on the matter.

The Chairman decided that the members should give their comments in the matter and the collated views will be forwarded to the National Blood Council for their opinion.

WEST BENGAL

Item No. 20 : Consideration of the amendment of Rule 63, Rule 77 and similar other Rules of the Drugs and Cosmetics Rules 1945 to avoid certain anomalies in the duration of licence.

The matter could not be discussed due to the absence of any representative from the State of West Bengal.

ORISSA

Item No. 21 : To consider the status of some pharmacopoeial drugs for manufacture and sale.

The members discussed on the Agenda points indicated by the Drugs Controller, Orissa. The members offered their affirmative views on the questionnaire points from (i) to (iv).

On the questionnaire point No. (v), the members expressed their views that products included in the Extra pharmacopoeia (Martindale), which are being marketed at present in different brand names in the Indian market, shall not be treated as official formulations.

Item No. 22 : Consideration for the amendment in Schedule 'K' of the Drugs and Cosmetics Rules to check the exorbitant price charged by the medical practitioners and nursing homes.

During the discussion of the Agenda, the members felt that such cases where the Medical Practitioners charged exorbitant price for drugs, would be brought to the notice of the Medical Council of India.

DADRA & NAGAR HAVELI

Item No. 23 : Consideration of the question whether Ampicillin and Cloxacillin combination of a drug can be packed individually in two separate capsules for better stability.

The members discussed the matter and decided that the practice of manufacturing by filling Ampicillin powder in a separate capsule in the manufacture of Ampicillin and Cloxacillin combination capsules, should not be allowed.

Item No. 24 : Consideration of the question whether sanitary pads be classified as drugs.

The Chairman requested the Assistant Drugs Controller (India), Silvassa to forward the copy of the judgement given by the Hon'ble Bombay High Court, to take further necessary action in the matter.

HARYANA

Item No. 25 : Consideration for the amendment in Section 26-A of the Drugs and Cosmetics Act to include the word 'Stock' in the last line of Section 26-A, after the word 'Manufacture'.

The members discussed the matter and decided that the issue should be reviewed carefully. Sometimes, 'Stocking' of banned drugs (under Section 26A) may be needed for further disposal, like withdrawal of a stock, to destroy a stock, etc. The Drugs Controller, Haryana has been requested to review the issue and to intimate the committee under which circumstances, the particular provision is needed by him.

GOA

Item No. 26 : **Consideration as to whether the storage condition mentioned on the label of a drug should be insisted upon at the wholesalers and retailers level.**

The members appreciated the Agenda point and felt that it is necessary to come to a conclusion under which circumstances the retailers and wholesalers could store the drugs before the distribution and sales.

The Chairman advised the members to form a sub-committee including the members from the IDMA, OPPI and Chemists and Druggists Association. The sub-committee will examine the issue and forward their expert comments to be considered by the DCC. The sub-committee was formed with the following members :-

1. The Commissioner, FDA, Maharashtra	-	Chairman
2. The Drugs Controller, Goa	-	Member Secretary
3. The Jt. D.C.(I) (DGHS Hqrs.)	-	Member
4. The Drugs Controller, Orissa	-	Member
5. The Drugs Controller, Assam	-	Member
6. The Drugs Controller, Tamilnadu	-	Member
7. The Drugs Controller, Kerala	-	Member
8. The Drugs Controller, Rajasthan	-	Member
9. The Drugs Controller, Punjab	-	Member

The sub-committee will co-opt the members from various associations and other expert agencies.

Item No. 27 : **Consideration for the uniform pack size for ointments under Rule 105 of the Drugs and Cosmetics Rules.**

The members discussed the matter and principally agreed with the views of the Drugs Controller, Goa. The Chairman decided that the matter will be examined and necessary amendments will be done in the Drugs and Cosmetics Rules to provide the standard pack size for the ointment products in general.

SUPPLEMENTARY AGENDA ITEMS

CENTRAL AGENDA

Item No. 1 : **Consideration of extension of shelf life of Rifampicin capsules in Schedule 'P' in Drugs and Cosmetics Rule and modification of packaging of Ethambutol tablets.**

Both the issues, extension of shelf life of Rifampicin capsules and packaging system of Ethambutol tablets were discussed in the meeting.

Dr. Tom Frieden, the guest member from WHO, SEARO, explained the current scenario in the global market in respect of shelf life of Rifampicin capsules and packaging of Ethambutol tablets.

All the members agreed that necessary stability studies are required to be performed to consider the extension of shelf life of Rifampicin capsules and also to select proper packaging system for the Ethambutol tablets.

The Chairman requested Dr. Vinay Nayak, the expert member to take up the issue and to forward necessary guidelines to be taken up by the Committee.

Item No. 2 : **Use of Saccharin Sodium and other artificial sweeteners in oral liquids and other preparations meant for paediatric use.**

The recommendation for the use of Saccharin Sodium in paediatric preparations made by the Indian Pharmacopoeia Committee has been discussed in the meeting.

The Chairman decided that once the minutes of I.P.Committee will be received, the matter will be circulated to all the members and experts. The DCC will take the decision after obtaining the comments from the experts.

AGENDA ITEMS FROM THE STATES

DELHI

Item No. 3 : Proposals and clarifications on sections and rules under the Drugs and Cosmetics Act and Rules thereunder.

Item No.3.1 :Consideration of the question whether the drugs banned under Section 26-A of Drugs and Cosmetics Act are applicable to such drugs used for Veterinary purpose.

The Chairman intimated the members that matter will be reviewed and the members will be informed accordingly.

Item No.3.2 : Consideration of the proposal for introducing new sections in the Drugs and Cosmetics Act for offences committed by an approved testing laboratory.

The members discussed the matter in the meeting. At present, Drugs and Cosmetics Rules (Rule 150-k) permits withdrawal and suspension of approvals given to the approved testing laboratories. However, there is no penal action prescribed under the Act in respect of the offences committed by an approved testing laboratory. In this connection, it may also be noted that there is no statute of an approved laboratory under the provisions the Act.

The members requrested the Drugs Controller, Delhi to review the Agenda and to forward a draft proposal justifying the incorporation of the penalty clause at the appropriate place of the Act for offences made by an approved laboratory.

TAMILNADU

Item No. 4 : Clarification on the regulatory control of Ayurvedic products.

Item No.4.1 : Consideration of manufacturing licence for herbal cosmetics containing chemical preservatives and stabilizers.

The Drugs Controller, Tamilnadu desired to know whether herbal cosmetic products (Ayurvedic, Unani and Siddha) can be construed as "cosmetics or herbal" products to decide the issue of manufacturing licence either in Form 32 or in Form 25D.

The members recommended that Form 32 should be used in case of cosmetics manufacturing licence.

Item No.4.2 : Consideration for sale licence for Ayurvedic drugs and other ISM drugs.

The members decided to refer the matter to ISM for consideration in Ayurvedic DTAB.

Item No.4.3 : Consideration of self generated alcohol in Asvas and Aristam.

The maximum content of self generated alcohol in Asvas and Aristam, etc. should be scientifically determined and the same should be adopted for the purpose of spiritual preparation Act and in the Drugs and Cosmetics Rules (Rule 161).

The members decided to refer the matter to the ISM Division for their expert comments.

KARNATAKA

Item No. 5 : Samples of raw materials used in the manufacure of drugs for test and analysis.

The Drugs Controller, Karnataka intimated the members that the Drugs Inspectors under Rule 52(4) can draw samples of drugs manufactured on the premises and send the same for test and analysis. According to him, many a times it is necessary to draw samples of other raw materials which are used in the manufacturing process. For this reason, the Drugs Controller, Karnataka desired that Rule 52(4) may be amended to enable the sampling of raw materials that are used in the preparation of drugs.

The members discussed the issue in detail and came to the conclusion that under Section 22 the Drugs Inspectors are already empowered to draw samples of any drug or cosmetics which is being manufactured or being sold or stocked or exhibited or offered for sale or is being distributed.

Thus the members felt that no further amendment is need in Rule 52(4) for the said purpose. The Section 22(b) will take care of drawing necessary samples of raw materials from the manufacturing premises.

MAHARASHTRA

Item No. 6 : Therapeutic claims made on the labels of Tooth pastes, Shaving Creams, Hair Oils and Shampoos.

The Joint Commissioner, FDA, Maharashtra, placed on Agenda stating that there are many tooth pastes, shaving creams, hair oils and shampoos which make therapeutic claims on the label. BIS does not permit therapeutic claim on the labels of cosmetics. Therefore, such products are not as per the standards made in the provisions of the Drugs and Cosmetics Act and Rules thereunder. He desired to know the views of the members.

The matter was discussed in the meeting and it has been decided that cosmetics like tooth paste, shaving cream, hair oil and shampoo, etc. making therapeutic claim on the labels are to be considered as 'drugs'.

GUJARAT

Item No.7.1 :Proposal to make amendment in Rule 148(1)(b) related to the manner of labeling of cosmetic products.

The Commissioner, FDA, Gujarat referred the existing provisions of Rule 148(1)(b) wherein it is mentioned that the inner and outer label of a cosmetic product should provide the name and principal place of business of the manufacturer. He desired that the words "principal place of business" may be substituted by the words "address of the manufacturing premises".

The Chairman decided that the matter may be taken up by the Expert Standing Committee for necessary examination and recommendation.

Item No.7.2 : Consideration to make amendment in Section 25(4) of the Drugs and Cosmetics Act, pertaining to the report of the Government Analyst, and some changes in Forms 27, 28, 27-A, 28-A, 27-F, 28-F, 28-D, 27-D and in Rules 27, 75(A), 76, 79(A), 65(2) and 66 of the Drugs and Cosmetics Rules.

The Commissioner, FDA, Gujarat desired to have some changes in some of the Sections of the Rules as well as in some Forms under the Drugs and Cosmetics Rules as mentioned in the titile of the Agenda. For this purpose, he brought certain write-ups on 22.9.1998 for the DCC meeting. However, the Agenda items were not much clarified in his write-ups and could not be discussed in detail in the open meeting.

On his permission, the Chairman suggested that he may take up the issues with Expert Standing Committee for necessary examination and recommendations.

ANDHRA PRADESH

Item No.8.1 :Consideration of drawing of samples for test and analysis from blood and blood components.

The Drugs Controller, Andhra Pradesh referred that there is no laboratory authorized under the Drugs and Cosmetics Act to test / analyse the blood and blood components. It is necessary to provide funds to State Government for the establishment of blood testing laboratories.

Since this is a specific matter, the Chairman suggested that the Government of Andhra Pradesh may take up the matter directly with NACO for obtaining necessary funds for the establishment of blood testing laboratories in the State.

Item No.8.2 : Consideration to regulate the misleading advertisements in relation to the curative / preventive action of AIDS on the use of drugs manufactured under Indian System of Medicine and Homoeopathy.

The Chairman intimated that steps have already been taken to weed out such misleading advertisements by regulating the provisions of DMR(OA) Act.

Discussion with the Associations viz. OPPI, IDMA, Chemists & Druggists Association and Consumer Organisation.

In the 32nd DCC Meeting various organizations, namely, OPPI, IDMA, Chemists & Druggists Association and Consumer Organisations have been invited to express their views before the State Drugs Controllers.

(i) The members from the OPPI advocated the inclusion of OTC drugs in the Drugs and Cosmetics Rules.

The Chairman intimated that the matter has already been taken up by the DCC meeting.

(ii) The members from the IDMA desired certain clarifications in respect of PMS studies on new drugs.

The Chairman requested them to take up the issue separately as it pertains to new drugs.

(iii) The members from the All India Organisation of Chemists and Druggists attended the meeting and have represented for some irrational issue of retail sale licences in some of the pockets of the country.

The Chairman requested the members to note it down and take necessary remedial action in this matter.

(iv) Nobody represented from the Consumer Associations to meet the members of the DCC.

The meeting ended with the Vote of Thanks to the Chair.

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Annexure – I
(Item no. 2 of the 32nd meeting)

Statement showing the action taken on the decisions taken at the 31st Meeting of the Drugs Consultative Committee held in New Delhi on the 21st & 22nd August 1997.

NO.	SUBJECT DISCUSSED	DECISION TAKEN	ACTION TAKEN
(1)	(2)	(3)	(4)
1.	Consideration of the proposal for curtailing the number of licences required for stocking, distribution or sale of drugs.	In absence of any comment from the members within the stipulated time period, the committee felt that the proposal may be taken up and the sub-committee report may be accepted for necessary amendments in the Drugs & Cosmetics Rules.	The subcommittee report has been accepted and proposed for DTAB. The issue will be taken along with the enhancement of fees structure which is pending for decision in DCC.
2.	Consideration of inclusion of Buprenorphine in Schedule X in the Drugs & Cosmetics Rules.	It is proposed that the extent of abuse should be studied in the Addiction Centres located in Govt. Hospitals by taking detailed history of the drug induced addiction coming to the centre for counseling and deriving longitudinal studies of Buprenorphine abused cases in such cross-section with reference to abuse due to other drugs, viz. Pentazocine, Diazepam, etc.	Comments received only from J&K, Haryana, TamilNadu and West Bengal suggesting to include Buprenorphine in Schedule X.
3.	Consideration of stocking of drugs labeled as Physician's	Members agreed to the sub-committee's report for necessary	Proposal is being sent for draft notification to MOH.

	samples in residential premises and unlincesed premises.	amendment in the Drugs & Cosmetics Rules.	
4.	Consideration of publication of the names of the manufacturers of the not of standard quality drugs in the press and other actions to be taken.	DDCI, West Zone will give a write-up on the matter.	Write up from the DDC(I) West Zone received for consideration.
5.	Consideration of powers to prosecute under DMR (OA) Act, 1954.	The Chairman decided that a sub-committee to be constituted.	The subcommittee is merged with a high power committee to develop the ideas, policies and guidelines under DMR Act. The report of the High Power Committee is awaited.
6.	Consideration of the question whether animal food preparations which are fortified with vitamins are to be drugs.	The DCC decided that the reconstituted subcommittee will study the matter.	The subcommittee report is not received. On telephone enquiry, the Chairman of the subcommittee intimated that he will submit a progress report by 10th Sept., 1998.
7.	Consideration of imported raw materials of B.P. and USP standards in respect of Calcium Pentothenate.	The Commissioner, FDCA Gujarat will give a write-up.	Write up not received from the Commissioner, FDCA, Gujarat. Also, referred to 8th Govt. Analyst Conference and a note on the issue is placed for consideration..
8.	Consideration of the examination of the extent and	The DCC decided that the matter should be examined by a subcommittee	The subcommittee requested for the extension of time upto March 99 to complete

	conditions of exemption provided under point No. 10 of Schedule 'K' for milk preparations and cereal preparations, fortified with vitamins and minerals, to be used for drugs – Classification of products containing Protein hydrolysates, Vitamins and Minerals, etc.	under the chairmanship of ADG, PFA.	the report. Status position of the report placed for consideration.
9.	Consideration of maintaining control reference samples by the Cosmetics manufacturers.	BIS testing laboratories may be requested to test the Cosmetic products and the laboratories may be given legal status.	A list of BIS Laboratories is being prepared in this matter. In 8th Govt. Analyst Conference, it has been decided that reference samples should be kept by the Cosmetic manufacturers. The DCC may note and recommend the same.
10.	Consideration of the issuance of conclusive test reports by PLIM Laboratory, Ghaziabad.	It is decided that the matter should be taken with the Secretary, ISM.	No positive response has yet been received in this matter. The matter will be taken up in 32nd DCC with the Jt. Secretary, ISM directly in the meeting.
CENTRAL AGENDA			
11.	Consideration of the proposal to amend rule 64 so as to prohibit or restrict excessive concentration of Chemists' Shops at a particular location.	A subcommittee will give its report by six months.	Report received suggesting amendment of Rule 64 for consideration.

12.	Proper amendment under rule 121 of Drugs & Cosmetics Act related to test for freedom from abnormal toxicity.	The members agreed to amend the rule.	46th DTAB Committee agreed to amend the rule.
13.	Proposal regarding the monitoring of banned drugs in the country.	Each State should forward the data, quarterly, in respect of banned drugs to DCGI.	Quarterly Report not received from the States. The matter may be discussed in 32nd DCC.
14.	Proposal regarding monitoring on quality / efficacy of the Biological products (Human / Veterinary) including veterinary drugs.	Decided that each State will identify one Inspector or ADC responsible for monitoring the quality of the Veterinary drugs and send the names to DCG(I), to forward the same to IVRI.	Members may agree to remove the word 'Human' from the title of the agenda.
15.	Proposal regarding incorporation of 'best use before' on marking clause of cosmetic product packs.	Members desired that BIS should decide and intimate that whether all the ingredients to be given or only the critical ingredients to be given on the label.	Comments from BIS is still awaited.
16.	Consideration of proposal to revise specifications of condoms under Scheduel 'R' as per the recommendations of WHO Guidelines issued in 1995.	The members agreed to amend the rule.	The 46th DTAB members agreed to amend with regard to water leakage test, Airburst volume and Pressure test.
17.	Proposal regarding suitable amendment under Entry No.27 of the banned drugs	The members after discussion requested the Chairman to address the matter to Consumers' Organisations,	Requested comments from two women organisation at Bombay and Delhi. Final reports from them are still awaited as both

	notification in respect of fixed dose combinations of Oestrogens and progestin.	particularly Women Organisations for their opinion.	the organizations required some clarifications. The names of the organization with whom the communications have made are- (i) Forum for Women's Health Kandivali (E), Bombay. (ii) Saheli, Defence Colony, Delhi
18.	Consideration of the proposal to amend Rules 74(J), 78(i) and 65(17) (b) of the Drugs and Cosmetics Rules, 1945 for expeditious recall of impunged samples of drugs by the manufacturer and sales outlets.	Decided that the format of the certificate to recall the drugs will be forwarded by the FDA, Maharashtra to DCGI.	A format used for recall of substandard drug is forwarded by Jt. Commissioner FDA, Maharashtra in Marathi Language. Agenda is to be discussed again in 32nd DCC. The format forwarded by the Joint Commissioner, FDA, Maharashtra placed along with the minutes of the 45th DTAB for consideration.
19.	Consideration of the proposal to amend Drugs and Cosmetics Rules, 1945 to grant exemption under certain specified conditions to peripheral institutions run by Government which are collection for transfusion of whole human blood under emergency situations.	DCC decided that the matter should be examined by a subcommittee.	Subcommittee report received with the comments that exemption under specified condition to be provided only to the Military and Defence Peripheral Institutions.
20.	Consideration of the proposal to insert the rule 148 provisions relating to safety testing of cosmetics with	The members agreed to amend the rule.	Proposal is under the consideration of DTAB.

	minimal use of animals.		
21.	Matters concerning grant or renewal of licences to manufacture Large Volume Parenterals (LVPs).	a) The Chairman desired that Commissioner FDA, Gujarat and Maharashtra would forward the information about the Loan Licence Holders of LVP. b) Necessary legal opinion may be sought from the Department of Legal Affairs.	Information received only from Commissioner FDA, Maharashtra is placed. The Agenda will be discussed again in 32nd DCC.
22.	Consideration of the proposal to omit Amaranth, Green –S, Fast Red E from specified colours listed under rule 127 of the Drugs & Cosmetics Rules, 1945.	The members agreed to amend the rule.	DTAB agreed to omit the three colours from specified colours listed under Rule 127.
23.	Consideration of the proposal to insert under Schedule H Steroidal Ophthalmic preparations.	The members agreed that Steroidal Ophthalmic preparations should be brought under Schedule H list of the Drugs and Cosmetic Rules.	DTAB agreed to the suggestion and recommended for inclusion in Schedule H.
24.	Grant of licences on Form 20B and 21B for wholesale of drugs in accordance with provisions of Rule 64 of the Drugs & Cosmetics Rules, 1945 – Clarification concerning qualification and experience of competent persons.	The members felt that the matter can be settled by providing the following amendment in the Rule 64, in the second line the word "with" should be read as "and".	DTAB agreed with the suggestion made by the DCC.

25.	Consideration of the proposal to amend relevant rules of the Drugs and Cosmetics Rules, 1945 with regard to upward revision of fee structure prescribed for grant / renewal of sales and manufacturing licences including Homoeopathic, Ayurvedic, Cosmetics and testing of drugs and enhancement of the period of sale licences.	The DCC decided that the matter should be examined by the subcommittee.	The subcommittee report is not received. On telephonec enquiry, the member Secretary intimated that the report will be forwarded by 10th September, 98 by Joint Commissioner, FDA, Maharashtra.
26.	Consideration of the proposal to amend Schedule F-II in respect of standards for surgical dressings, viz. Gauze and Bandages.	The Chairman decided that comments of BIS should be taken in the matter.	Final report has not been received from the Textile Section of BIS.
27.	Proposal regarding inclusion of GOOD CLINICAL TRIAL REGULATIONS IN INDIA under "Schedule Y" of Drugs and Cosmetics Act and Rules thereunder.	The DCC decided that the draft guideline will be circulated to all the members for their comments and the comments received may be examined by a special subcommittee constituted for the purpose.	No Comments has been received from the DCC members.
28.	A proposal regarding rationalization of Fixed Dose Combinations (FDCs) moving in the market with various proportion in respect of	The Chairman opined that membes should forward their comments to rationalize the formulations containing paracetamol.	The issue relating to the rationalization of formulation containing paracetamol and Ibuprofen is under the consideration of the ore group appointed by the Hon'ble Suppremme Court. The decision of the core

	following (a) Dextropropoxyphene with Paracetamol, (b) Ibuprofen with Paracetamol and (c) Diclofenac Sodium with Paracetamol.		group will be circulated after finalization. For other two formulations please refer to the placed material.
29.	Consideration of inclusion of all "Schedule G" drugs in "Schedule H" and the resultant omission of "Schedule G" from the Rules.	The DCC decided that the matter should be examined by a subcommittee.	Subcommittee report is not received. On telephonic enquiry the Commissioner, FDA, Gujarat (Chairman) intimated that a report in this regard will be forwarded by him by 10th September 1998.
30.	Proposal for inclusion of a Rule regarding prohibition against altering inscription of containers, labels or wrappers of cosmetics.	The Chairman desired that members should send their comments, if they need any action in the matter.	46th DTAB agreed with the decision made by the DCC. Inclusion of the appropriate is under process.
31.	Consideration of the proposal for reducing the period of training programme of 2 years which is provided under Rule 44 (a) and 44 (b) of the Drugs and Cosmetics Rules, 1945.	The Chairman desired that all the members should forward their opinion in the matter.	Comments received only from the Drugs Controllers A.P. Rajasthan and the Commissioner FDA, Maharashtra suggesting to reduce the time period.
32.	Proposal to amend Item No. 56 of banned drugs Notification vide GSR 633(E) dated 13.9.95.	Advisor ISM should be asked to include the hard gelatin capsules in their Schedule as many Ayurvedic medicine now being filled and sold in capsule form.	The Jt. Secretary ISM intimated that gelatin is an inactive neutral component in ASU Drugs. He requested that Ministry of Health should take immediate action to rescind entry No. 56.

33.	Proposal regarding the status of condoms and surgical sutures added with colours.	The Drugs Controller, Karnataka, will give some specific colours, other than the colours already mentioned in the Rule 127(i), which can be used in the manufacturing of Condoms.	No report is received in this regard from the Drugs Controller, Karnataka.
34.	Proposal for inclusion of certain workings in entry 52 of banned drug under Notification No. GSR 57 (E) dated 7.2.95.	All the members unanimously agreed for necessary change in the entry No.52 of the Banned Drug Notification GSR 57 (E) dated 7.2.95.	The matter is related to the addition of words in category 52 under GSR 57 (E) that "patent proprietary ORS shall not contain mono or Poly-Saccharides or Saccharin as sweetening agent". Use of Saccharin is under review by the I.P. Committee. No action has yet been taken in this regard.
35.	Proposal for modification of the content of the prescription under Rule 65 (10).	In view of the Hon'ble Supreme Court judgement, some modifications are needed in the prescriptions made by the Registered Medical Practitioners. The modifications fall under the provisions of Rule 65 (10). So, DCC desired that a primary opinion may be taken from the Medical Council of India.	No comments are received from the Medical Council of India.
36.	Proposal to include provisions to direct withdrawal of stock of drugs in case of loan licence.	The Chairman requested the Commissioner, FDA Maharashtra to take opinion from the Legal Dept. of their State and forward the same to DCG(I)	The Jt. Commissioner, FDA, Maharashtra intimated that it will take some more time to have the legal opinion on the matter.
31st DCC Supplementary			

Agenda			
37.	Reconsideration of exemption from the provisions of sale licence from selling / distribution of White Petroleum Jelly (Vaseline) and inclusion thereof under Schedule K of the Drugs & Cosmetics Rules, 1945.	The members unanimously decided that the said item could be given exemption under Schedule K at any appropriate entry as "non-perfumed White Petroleum Jelly".	46th DTAB recommended the decision made by the DCC.
38.	Reconsideration of the constitution of Expert Standing Committee for in-depth examination for amending provisions of Drugs & Cosmetics Act, 1940, and Rules thereunder.	The members decided that Commissioner, FDCA, Gujarat, shall be the Chairman of the said Committee and Shri B R Wadhawan, Asstt. Drugs Controller (I), shall be the Member-Convenor	No proposal is received in this regard.